

Australia approves COVID-19 rapid antigen self-tests

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COVID-19 self-tests (home use) approved by TGA

The Therapeutic Goods Administration (TGA), the medicine and therapeutic regulatory agency of the Australian Government, has approved two COVID-19 self-tests (home use tests) for supply in Australia from 1 November 2021.

Both tests have been manufactured by Chinese firm Hangzhou Alltest Biotech, and will be supplied within Australia by AM Diagnostics.

The All Test COVID-19 Antigen Rapid Test (Oral Fluid) is a qualitative membrane-based immunoassay for the detection of SARSCoV-2 Antigens in human oral fluid specimen.

The All Test SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human swab specimen.

These tests are intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).